

BEST AVAILABLE COPYPatent
Atty. Dkt. No. LYNN/0120.A**REMARKS**

Claim 26-37, 40-42 and 44-49 stand rejected under 35 U.S.C. 102(a) as being anticipated by European Patent No. 0 905 227, issued to Campestrini, *et al.* Campestrini discloses a liquid anhydrous composition comprising a mono- or di-peracid. (Campestrini, Abstract).

Applicant claims, *inter alia*, a solid composition of one or more dipercarboxylic acids that are solid at room temperature and soluble at sterilizing concentrations in water. (Claims 26).

To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

An additional requirement for providing a *prima facie* case of obviousness is that the Examiner must provide a basis for combining or modifying the cited references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

Applicant respectfully asserts that the Examiner has failed to provide a *prima facie* case of obviousness because Campestrini does not disclose a solid dipercarboxylic acid as claimed by Applicant.

The Examiner further failed to provide a basis for modifying Campestrini as required for a *prima facie* case of obviousness.

Therefore, because the Examiner has failed to provide a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection of independent claim 26 is respectfully requested as well as for the other rejected claims that depend, directly or indirectly, therefrom.

Claims 26-37, 40-42 and 44-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,503,765 issued to Schepers, *et al.* and U.S. Patent No. 5,268,003 issued to Coope, *et al.* Schepers discloses a non-aqueous liquid composition of dipercarboxylic acids that have low solubility in the non-aqueous liquid. The dipercarboxylic acids disclosed by Schepers are mono- or di-percarboxylic amido or imido acids. (Schepers, col.

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8, ln. 43-45). These compounds are high molecular weight compounds and Schepers does not disclose their solubility in water. However, because of their high molecular weight, these compounds disclosed by Schepers would not be considered to be soluble in water at concentrations high enough to form a sterilizing solution. This is confirmed by Coope, the secondary reference, saying that "detergent formulations containing a peroxyacid bleach system ... will usually also contain surfactants ... [that] function as a structuring system to suspend the water-insoluble amido peroxyacids in water or any other solvent carrier." (Coope, col. 5, ln., 44-50).

Applicant believes that the Examiner has cited *In re Thuau*, 57 USPQ 324 for the law that a new use for an old composition does not render the old composition patentable. Applicant agrees.

However, Applicant asserts that certain limitations in the pending claims make the claims distinguishable over the cited references by much more than a mere statement of the intended use of an old composition. It is these limitations that place the claims beyond the reach of the ruling of *In re Thuau*. In other words, *In re Thuau* is not dispositive here, because the patentability of the claims does not rest upon a mere new use of an old composition, but rests upon a new and nonobvious composition.

In the case of *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), the Court of Appeals for the Federal Circuit discussed the patentability of claims to a metabolite DCL in light of a prior art patent disclosing the drug loratadine. Evidence showed that there was no express disclosure of DCL and no mention of the metabolites of loratadine in the prior patent, yet DCL was necessarily formed as a metabolite by carrying out the process disclosed in the earlier '233 patent. After holding that the inherent result of administering loratadine to a patient is the formation of DCL, the Court went further to provide guidance to Applicants for properly claiming inventions when "bare compound claims" are unpatentable.

The Court advised that:

A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in Kratz and Bergstrom, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). ... The '233 patent would not provide an enabling disclosure to anticipate such claims because, for

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instance, the '233 patent does not disclose isolation of DCL. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003)

Applicant asserts that its present claims are drafted consistent with the foregoing advice of the Federal Circuit, because independent claim 26 is not directed to bare dipercarboxylic acids, but to a combination of components in a measured amount and substantially free from other organic compounds. Applicant is not claiming an old composition as dealt with by *In re Thuau*, but instead is claiming a combination of components including an exothermic control agent. The Schepers and Coope patents do not suggest any need for an exothermic control agent as in the presently claimed composition. Reconsideration and withdrawal of the rejection is requested.

Schepers does not disclose a solid particulate composition, but rather discloses a non-aqueous liquid composition of dipercarboxylic acids that have low solubility in the non-aqueous liquid. The dipercarboxylic acids disclosed by Schepers are mono- or di-percarboxylic amido or imido acids. (Schepers, col. 8, ln. 43-45). These compounds are high molecular weight compounds and Schepers does not disclose their solubility in water. However, because of their high molecular weight, these compounds disclosed by Schepers would not be considered to be soluble in water at concentrations high enough to form a sterilizing solution. This low water-solubility is confirmed by Coope, the secondary reference. (Coope, col. 5, ln., 46-50).

Applicant claims, *inter alia*, dipercarboxylic acids that may be stored as a solid at room temperature and that are soluble in water to form an aqueous solution having a concentration of at least 0.1 wt. %. (claim 26). The 0.1 wt % concentration is a concentration that is high enough to form a sterilizing solution.

Schepers does not disclose, teach, suggest or motivate that the high molecular weight peracid compounds that are discussed therein may be dissolved in water at a concentration of at least 0.1 wt. %. Schepers discloses solubility of various compounds in non-aqueous solutions, but not in aqueous solutions as claimed by Applicant. (Schepers, col. 12 – col. 14). Schepers discloses peroxyacid concentrations of between 0.1 to 10%, but these concentrations are not in an aqueous solution. Rather, the peroxyacids are “substantially insoluble” (Schepers, col. 3, line 57) in the non-aqueous liquid composition of the Schepers’ invention. (Schepers, col. 4, ln. 30-31). Therefore, Schepers does not teach, suggest or motivate that there exists dipercarboxylic acids

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that are a stable solid and that can be solubilized in water to form a sterilizing solution as claimed by Applicant.

To establish a *prima facie* case of non-obviousness, there must be (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one having ordinary skill in the art, to modify or to combine reference teachings; (2) a reasonable expectation of success; and (3) all the limitations of the claimed invention disclosed. See MPEP, § 2143.

Schepers does not teach, suggest, motivate or disclose that a dipercarboxylic acid may be stored as a solid and then solubilized in water to form a sterilizing solution having a concentration of at least 0.1 %. In fact, the acids disclosed by Schepers are all high molecular weight acids that are not soluble in water at high enough concentrations to achieve a 0.1 % concentration as claimed by Applicant. Therefore, Schepers does not present a *prima facie* case of obviousness against Applicant's claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

Coope discloses the same high molecular weight acid types as Schepers. Coope specifically states that the acids disclosed therein are not soluble in water. Coope states, "When in liquid form, the surfactants serve not only to clean but importantly function as a structuring system to suspend the water-insoluble amido peroxyacids in water or any other solvent carrier." (Coope, col. 5, ln., 46-50). Since the acids disclosed by Coope are not water soluble, Coope does not disclose, teach or suggest a dipercarboxylic acid that is soluble in water at concentrations sufficient to form a sterilizing solution as claimed by Applicant. (claim 26).

Because neither Coope nor Schepers disclose, teach, or suggest a dipercarboxylic acid that is soluble in water at sterilizing concentrations, a *prima facie* case of obviousness has not been presented. Indeed, both Coope and Schepers disclose high molecular weight acids that are not soluble in water, as stated by Coope.

Applicant believes that the Examiner must give full consideration to the functional limitations of the claim when determining obviousness. Functional limitations should be given patentable weight when the function limitations are nonobvious over the prior art. See *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Here, claim 26 includes the limitation of "one or more dipercarboxylic acids that are solid at room temperature and soluble at sterilizing concentrations

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in water.” The compounds of this limitation are limited by their chemical class, i.e., dipercarboxylic acids, and are further limited to only those dipercarboxylic acids that function to form a “solid at room temperature” and that are “soluble at sterilizing concentrations in water.” These functional limitations are neither disclosed nor suggested by Schepers or Coope. Reconsideration and withdrawal of the rejection is requested.

Attention is drawn to claim 31, which claims only a certain six C5 to C9 dipercarboxylic acids and combinations thereof. By contrast, Schepers says that “[t]he peroxyacids used in the compositions of the invention are amide or imide peroxyacids . . .” (Schepers, col. 3, lines 8-9). Coope discloses “a new series of amido-type peroxydicarboxylic acids.” (Coope, col. 2, lines 43-44). Applicant asserts that there is no disclosure of the claimed C5-C9 dipercarboxylic acids, and that there is no suggestion to modify the teaching of Schepers or Coope to use these acids. An indication of the allowability of claim 31 is requested.

Claims 26-37, 40-42 and 44-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,437,868 issued to Oakes, *et al.* and U.S. Patent No. 5,049,298 issued to Ploument, *et al.* Oakes has disclosed using a liquid dipercarboxylic acid as an antimicrobial agent. Oakes, using the information known to those having ordinary skill in the art, does not teach or disclose that a SOLID dipercarboxylic acid may be dissolved to form an aqueous solution that is a sanitizing solution, as Applicant claims.

On the other hand, Ploumen discloses solid dipercarboxylic acids that are *not soluble* in water. Ploumen states “The invention relates to a process for the preparation of bleaching granules containing a solid, *water-insoluble* peroxy acid and a hydratable inorganic material. (Ploumen, Abstract, emphasis added). Therefore, neither Ploumen nor Oakes describes, teaches or suggests that a diperacid may be stored as a solid and then dissolved to form sterilizing aqueous solution as claimed by Applicant.

Because neither of the cited references teaches nor suggests each and every limitation claimed by Applicant, and because the Examiner has failed to provide a motivation to combine or modify the cited references, Applicant respectfully asserts that a *prima facie* case of obviousness has not been presented. Reconsideration and withdrawal of the rejection of claim 26 is respectfully requested as well as the rejection of the other claims that depend, either directly or

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indirectly, from claim 26.

Claims 26-37, 40-42 and 44-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over and U.S. Patent No. 5,415,668 issued to Lagnemo, *et al.* Lagnemo discloses diacylated dipercarboxylic acids that are useful as a bleach. (Abstract). Diacylated dipercarboxylic acids are not dipercarboxylic acids but are instead dipercarboxylic that have been reactants in a chemical reaction to form an ester, the structure of which is shown in the Abstract. (Lagnemo, Abstract). Lagnemo discloses that there are some diacylated dipercarboxylic acids that are useful as bleaches because they are soluble in water to concentrations useful as a bleach. (Lagnemo, col. 2, lines 20-47). Lagnemo further discloses that a useful bleaching amount is 0.12 g of a diacylated dipercarboxylic acid or double that amount, 0.24 g, per 1000 ml of water. (Lagnemo, col. 18, lines 16-35). Such a formulation yields about 0.024 wt% diacylated dipercarboxylic acid in water. Furthermore, Lagnemo discloses that the ester undergoes hydrolysis when placed in water so that it breaks down into both dipercarboxylic acids and percarboxylic acids and when hydrogen peroxide is present, forms 2 moles of percarboxylic acid and one mole of dipercarboxylic acid. (Lagnemo, col. 2, lines 10-20).

Lagnemo does not suggest or teach that the diacylated dipercarboxylic acids can be dissolved in water at a concentration high enough to form a sterilizing solution, *i.e.*, greater than 0.1 wt% as claimed by Applicant. The amount of dipercarboxylic acid needed to form a bleaching solution is much less than the amount needed to form a sterilizing solution. Because Lagnemo fails to teach or suggest each and every limitation claimed by Applicant, reconsideration and withdrawal of the rejection is respectfully requested.

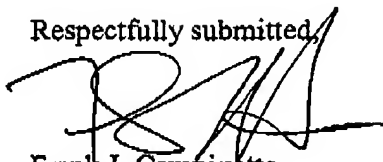
Applicant hereby files the attached declarations of each of the inventors. Declarations similar to the attached declarations were filed in the parent application of this pending divisional application and Applicant wishes them to be of record in this pending application.

In conclusion, Applicant submits that all remaining claims in the present application are entitled to allowance and such action is earnestly solicited. In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to

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charge the Deposit Account No. 50-0714/LYNN/0120.A of the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,



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